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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/852,666 05/07/97 CHADA

K UMD-1.0-037C

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HM22/0612

EXAMINER

KAM, C

ART UNIT	PAPER NUMBER
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1653

*25*

DATE MAILED:

06/12/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/852,666

Applicant(s)

CHADA ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 41-47 is/are pending in the application.
- 4a) Of the above claim(s) 41-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 45-47 are pending.

Applicants' response filed on February 7, 2001 (Paper No. 24) has been fully considered.

Claims 41-44 have been cancelled and a new claim 47 has been added.

### ***Rejection Withdrawn***

#### ***Claim Rejections - 35 USC § 112***

2. The previous rejection of claims 41-44, under 35 U.S.C. 112, first paragraph and second paragraph, is withdrawn in view of applicants' cancellation of the claims.
3. The previous rejection of claims 41-46, under 35 U.S.C. 112, second paragraph, regarding the inhibition of HMGI biological activity, is withdrawn in view of applicants' response and the biological function of HMGI is defined in the specification.
4. The previous rejection of claims 44-46, under 35 U.S.C. 112, first paragraph, regarding lack of adequate written description of HMGI protein-regulated promoter, is withdrawn in view of applicants' response and disclosure of the subject matter in the specification.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 45 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 45 and 46 are indefinite because the claims are dependent claims of a cancelled claim, and the metes and bounds of the claim cannot be ascertained.

6. Claim 47 is indefinite because of the use of the term “a fragment”. The term “a fragment” renders the claim indefinite, it is not clear which fragment of HMGI is, e.g., whether this fragment has the same biological function as HMGI. Does the fragment contain a DNA binding domain or a protein-protein interaction domain?

The previous rejection of claims 41-46, under 35 U.S.C. 112, second paragraph, regarding omitting essential steps such as determining binding affinity, measuring and quantifying the biological activity, is withdrawn in view of applicants' amended the method steps with a new claim 47.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 47 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim is drawn to a method for screening candidate compounds capable of inhibiting HMGI biological activity. The method comprises an immobilizing step using a HMGI protein or a fragment. However, the specification does not indicate which part of HMGI is the claimed fragment and whether this fragment has the HMGI function or contains a functional domain. The method also comprises steps of measuring the binding affinity of the compounds to the

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immobilized HMGI, however there is no description regarding the specific means for measuring the binding affinity. The method also comprises the steps for a cell-based assay using a DNA construct containing a reporter gene such as luciferase gene under control of a HMGI-regulated promoter such as human interferon- $\beta$  promoter (steps (e)-(h)), however, there is no data indicating the levels of reporter gene expression in the presence and absence of candidate compound being measured. Since it is not routine in the art to engage in *de novo* experimentation where the expectation of success is unpredictable, the skilled artisan would require additional guidance in order to practice the claimed method. Without such guidance, the experimentation left to those skilled in the art is undue.

The factors considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d at 731,737, 8 USPQ2d at 1400,1404 (Fed. Cir.1988)). The factors most relevant to this rejection are lacking of working examples, the amount of direction or guidance presented and the amount of experimentation necessary.

Regarding fragments, applicants argue that fragments are well known in the art and recognized by those skilled in the art, thus it is not necessary to disclose the limitations of a claimed process. Applicants also provide a list of fragments with structural variations including biologically active fragments and fragments containing special structural features. However, the argument is not persuasive because unspecified fragments which do not contain functional domains such as DNA binding domain of HMGI would not accomplish the claimed method. Therefore, it is necessary to specify the fragments with the biological function of HMGI or with the functional domains of HMGI for the claimed process.

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*Conclusion*

8. No claims are allowed.

Applicant's amendment of claims and new claim 47 necessitated the new ground(s) of rejection presented in this office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.  
Patent Examiner

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June 8, 2001

*Christopher S. Low*  
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